K070178

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

Aesculap Resorbable Pin

25 April 2007

APR 3 0 2007

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 3005673311

CONTACT: Matthew M. Hull, Regulatory Affairs Manager
800 258-1946 x 5072 (phone)
610 791-6882 (fax)

TRADE NAME: Aesculap® Resorbable Pin

COMMON NAME: Resorbable Orthopedic Pin

DEVICE CLASS: Class II

PRODUCT CODE: MAI

CLASSIFICATION: 21 CFR Section 888.3030: Fastener, Fixation, Biodegradable, Soft Tissue

REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

The Aesculap Resorbable Pin is intended for use in the fixation of fragments of non-load bearing bones, osteotomies, arthrodeses, meniscal tissue repair, and osteochondral repair.

DEVICE DESCRIPTION

The Aesculap Resorbable Pin is a small orthopedic fixation pin made from a copolymer material (Poly–L,DL -Lactide Co70/30) that is absorbed into the body over time.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Aesculap Resorbable Pin.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device.

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the Aesculap® Resorbable Pin is equivalent in materials and similar in use to the previously cleared Arthrex Meniscal Dart System (K983577) and the Bionx Smart Nail from ConMed Linvatec (K993074).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2007

Aesculap® Implant Systems, Inc.
% Mr. Matthew M. Hull
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K070178
Trade/Device Name: Aesulap® Resorbable Pin
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: January 19, 2007
Received: February 7, 2007

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruehwo
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: **Aesculap Resorbable Pin**

Indication for Use:

The Aesculap Resorbable Pin is intended for use in the fixation of fragments of non-load bearing bones, osteotomies, arthrodeses, meniscal tissue repair, and osteochondral repair.

Prescription Use ___X___ or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070178

(Optional Format 3-10-98)